

## REMARKS

### Status of the claims

With entry of the amendment, claims 29-33, 35-41, 43-48, and 55, 56, and 58-64 are pending in the application. In view of the amendments above and the arguments below, Applicants respectfully request reconsideration on the merits of the application, withdrawal of the rejections and objections, and allowance of the claims.

### Summary of amendments

The specification was amended to capitalize the trademarks SEPHADEX, AMBION and NEW ENGLAND BIOLABS. Independent claims 29 and 64 were amended to clarify that the first oligonucleotide, the Substrate Hybridization Domain of the first oligonucleotide, the Signal Template Domain of the first oligonucleotide, and the Template Hybridization Domain of the second oligonucleotide each consists essentially of the recited limitations. Similarly, claim 61, which depends from claim 29, was amended to clarify that the Substrate Hybridization Domain and Template Hybridization Domain each consists essentially of the recited limitations. Claims 55 and 56 have been amended to delete the phrase "at least." The amendments introduce no new matter.

### Objection to the specification

The specification has been objected to for not capitalizing the trademarks NYLON, SEPHADEX, AMBION and NEW ENGLAND BIOLABS. Applicants have amended the specification to capitalize the occurrences of SEPHADEX, AMBION and NEW ENGLAND BIOLABS. However, nylon is not a trademark, being defined at least by the Merriam-Webster dictionary as "any of numerous strong tough elastic synthetic polyamide materials that are fashioned into fibers, filaments, bristles, or sheets and used especially in textiles and plastics." Consequently, this term has not been capitalized. Applicants request that the objections to the specification be withdrawn.

### Rejection under 35 U.S.C. 112, first paragraph

Claims 55 and 56 stand rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Examiner asserts that the amendment of January 18, 2002 introduced new matter in the recitation a specific activity of "at least"  $7 \times 10^7$  or  $9 \times 10^7$  CPM per picomole. Applicants note that the probes made by the method of claim

29, from which claims 55 and 56 depend, encompass probes having specific activities of greater or less than  $7 \times 10^7$  or  $9 \times 10^7$  CPM per picomole. Therefore, in the interest of advancing prosecution, Applicants have amended claims 55 and 56 to delete the phrase “at least.” Accordingly, Applicants request that the rejection be withdrawn.

Rejection under 35 U.S.C. 112, second paragraph

Claims 29-33, 35, 37-41, 43-48, 55, 66 and 58-64 stand rejected under 35 U.S.C. 112, second paragraph. The Office Action states that these claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the recitation of a first oligonucleotide “consisting essentially of” certain domains. The Examiner asserted that, although the term “consisting essentially of” is recognized for allowing for the inclusion of additional ingredients in a composition so long as it does not alter the basic novel features of said composition, the term has not been defined in terms of what constitutes the basic and novel features of the oligonucleotide.”

Applicants respectfully submit that the transition “consisting essentially of” does not render the claims indefinite. Rather, it is well established that the transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps and to equivalents “that do not materially affect the basic and novel characteristic(s) of the claimed invention.” *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). The Examiner has cited no authority for the proposition that the term “consisting essentially of” has not been defined in terms of what constitutes the basic and novel feature of the oligonucleotide.” In fact, the United States Patent and Trademark Office has issued numerous patents with claims drawn to oligonucleotides “consisting essentially of” specified characteristics, or to methods employing such oligonucleotides.

Applicants note that claims 29-33, 35, 37-41, 43-48, 55, 66 and 58-64 are drawn to a method of labeling an oligonucleotide. The basic and novel characteristics of the invention are defined in the balance of the claim.

One of skill in the art would readily be able to discern the limits of the claim as encompassing methods employing oligonucleotides having the recited limitations, or oligonucleotides including an additional feature that does not interfere with the ability of the oligonucleotides to function according to the claimed method. In other words, the method requires: (1) hybridization of a first oligonucleotide having, from 3' to 5', a Substrate Hybridization Domain consisting essentially of a sequence of about 5 to about 20 nucleotides

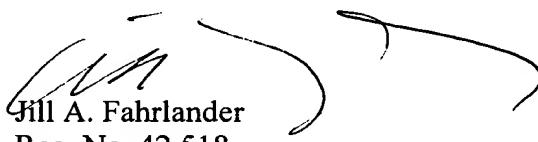
adjoining a Signal Template Domain consisting essentially of a sequence of about 5 to about 100 nucleotides that hybridizes to a second oligonucleotide comprising, from 3' to 5', a Template Hybridization Domain consisting essentially of a sequence of about 5 to about 20 nucleotides which is not detectably labeled, has 5 or more bases complementary to the Substrate Hybridization Domain of the first oligonucleotide, and is hybridizable to the Substrate Hybridization Domain of the first oligonucleotide, the Template Hybridization Domain adjoining a Target Binding Domain that is not detectably labeled and which comprises a nucleotide sequence heterologous to that of the Template Hybridization Domain and to that of the first oligonucleotide; and (2) extending the second oligonucleotide with a DNA polymerase in the presence of a labeled nucleotides to create an oligonucleotide Probe having from 5' to 3' an unlabeled Target Binding Domain adjoining a Template Hybridization Domain adjoining a labeled Signal Domain.

In other words, if a first or second oligonucleotide modified to include an additional feature retains the ability to hybridize so as to permit extension of the second oligonucleotide using a DNA polymerase to create a probe having, from 5' to 3', an unlabeled Target Binding Domain adjoining a Template Hybridization Domain adjoining a labeled Signal Domain, then the modification is an equivalent falling within the scope of an oligonucleotide "consisting essentially of" the recited claim limitations.

Applicants respectfully submit that claims 29-33, 35, 37-41, 43-48, 55, 56 and 58-64 are not indefinite and request that the rejection be withdrawn.

No fee is believed owing with this submission. If a fee has been inadvertently overlooked, please charge any additional fee due or credit any overpayment of fees to Deposit Account No. 50-0842.

Respectfully submitted,



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